



**Billing Code 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of an Exclusive Patent License: Agonist/Antagonist Compositions and Methods of Use**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Bull Run Capital, Inc. located in Vancouver, BC, Canada.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jaime M. Greene, Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: [greenejaime@mail.nih.gov](mailto:greenejaime@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:**

## **Intellectual Property**

U.S. Provisional Patent Application No. 61/340,063, filed March 12, 2018, now abandoned, titled “Agonist/Antagonist Compositions and Methods of Use”, HHS Ref No.: E-048-2010-0-US-01;

PCT Patent Application Serial No. PCT/US2011/028132, filed March 11, 2011, now abandoned, HHS Reference Number E-048-2010-0-PCT-02 titled “Agonist/antagonist compositions and methods of use”;

U.S. Patent 9,277,748 (Application No. 13/634,447) filed March 11, 2011, issued March 8, 2016, titled “Agonist/antagonist compositions and methods of use”, HHS Ref No.: E-048-2010-0-US-04;

Canada Patent Application Serial No. 2,792,878, filed March 11, 2011, HHS Reference Number E-048-2010-0-CA-03 titled “Agonist/antagonist compositions and methods of use”; and

U.S. Patent Application Serial No 15/010,830, filed January 29, 2016, HHS Reference Number E-048-2010-0-US-05, titled “Agonist/antagonist compositions and methods of use”.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: “Use of the TRVP1 antagonists BCTC, AMG9810, JYL-827, Capsazepine or IodoRTX combined with a TRVP1 agonist in a composition for the temporary incapacitation of a subject.”

This technology discloses novel compositions comprising a transient receptor potential cation channel subfamily V member 1 (TRPV1) receptor agonist and an antagonist in certain ratios which allow for the onset of agonist action followed by alleviation by antagonist action, and methods of use in personal defense and law enforcement.

Non-lethal means of temporarily incapacitating a person are needed for law enforcement and for personal protection. A common approach currently is to use pepper spray. Although current pepper sprays are effective, and relatively safe, for most individuals, they can be life threatening for people who suffer from asthma and have hypersensitive airways.

In order to reduce the length of time the pepper spray can cause the adverse effects that could result from extended exposure, inventors at NCI have created a composition comprising both an incapacitating pepper spray TRPV1 receptor agonist compound and a slower-acting TRPV1 receptor antagonist compound that reverses the effects of the agonist. The agonist/antagonist composition is intended to be used as an aerosol or spray, that, when administered, causes a painful stimulation and incapacitates a person for only a short period of time. This technology may fill a public health need by improving safety over currently available pepper sprays.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: November 9, 2018.

**Richard U. Rodriguez,**

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*National Cancer Institute.*

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